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J. Mitchell Jones
MEDLEN & CARROLL, LLP
Suite 350
101 Howard Street
San Francisco, CA 94105

EXAMINER	
LUM, LEON YUN BON	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,552	NELSON, BRYCE P.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *25 February 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 25 February 2005 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification never discloses the limitation of claim 23, wherein a "whole cell solution further comprises a cellular product". Instead, the specification at multiple locations on pages 2-7 states that a "cellular product may comprise whole cell solutions, lysed cell solutions, subcellular compartment solutions or a cellular mixture comprising combinations of whole cell solutions, lysed cell solutions, or subcellular compartment solutions", thereby indicating that the cellular product is a genus and includes the species of whole cell solutions. Since claim 23 recites the limitation of a cellular product as a sub-section of the whole cell solution, and this limitation is not supported in the

specification, the instant claim is rejected on the basis of new matter not disclosed in the specification and consequently, dependent claims 24-25 are also rejected as containing new matter.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 18-21, 26-27, and 29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kornguth et al (US 5,629,213).

In the instant claims, Kornguth et al teach an SPR biosensor system with an array of islands (i.e. arrayed solid surface), wherein each island may comprises a slightly different organic film for detection of a single analyte or the detection of multiple analytes, wherein the organic film may be antigens, immunoglobulins, receptors, or nucleic acids (i.e. addressable target molecules) that form the functional basis of an immunological sensor, and wherein the immunological sensor detects (i.e. detect the presence of an interaction) epitopes on bacteria or transformed cells (i.e. whole cells). See column 2, lines 29-51; column 3, lines 26-38; and Figures 1-3. Since Kornguth et al teach that the epitopes are on bacteria or transformed cells, the reference is interpreted to teach the presence of whole cells during detection.

With regards to claim 21, the specification on page 9, lines 4-6 define cell initiation molecules as proteins. Since Kornguth et al reference teaches that the organic film can be polylysine, the reference anticipates the instant claim. See column 3, lines 19-20.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kornguth et al (US 5,629,213) in view of Magnani (US 5,965,457).

Kornguth et al reference has been disclosed above, but fails to teach that the whole cell solution comprises stem cells.

Magnani reference teaches a sample of bone marrow, in order to provide a biological source of bone marrow stems cells that can be isolated using antibodies to CD34 antigen, and to apply the isolated stem cells to repopulate bone marrow of a cancer patient after ablative treatment. See column 1, lines 17-56 and column 2, lines 25-29.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Kornguth et al with a sample of bone marrow, as taught by Magnani, in order to provide a biological source of bone marrow stems cells that can be isolated using antibodies to CD34 antigen, and to apply the isolated stem cells to repopulate bone marrow of a cancer patient after ablative treatment. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a sample of bone marrow stem cells, as taught by Magnani, in the apparatus of Kornguth et al, since Kornguth et al teach that the SPR biosensor system can include immunoglobulin capture agents, and the CD34 antigen on bone marrow stem cells is one type of antigen that can be captured by immunoglobulins.

9. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornguth et al (US 5,629,213) in view of Magnani (US 5,965,457) as applied to claims 18 and 22 above, and further in view of Knowles et al (US 4,647,654).

Kornguth et al and Magnani references have been disclosed above, but fail to teach that said whole cell solutions further comprises a cellular product and wherein said cellular product is selected from the group consisting of lysed cells.

Knowles et al reference teaches a solution of lysed red blood cells, in order to perform a specific binding assay to isolate the Hb A_{1c} epitope on hemoglobin and to determine the amount of glucosylated Hb as an indication of a diabetic condition. See column 1, lines 12-43 and column 7, lines 20-33.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Kornguth et al and Magnani with a solution of lysed red blood cells, as taught by Knowles et al, in order to perform a specific binding assay to isolate the Hb A_{1c} epitope on hemoglobin and to determine the amount of glucosylated Hb as an indication of a diabetic condition. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including lysed red blood cells, as taught by Knowles et al, in the apparatus of Kornguth et al and Magnani, since Kornguth et al and Magnani teach specific binding assays on bone marrow samples, and the red blood cells taught by Knowles et al is one type of cell found in bone marrow (see Magnani, column 1, line 54). In addition, Kornguth et al and Magnani teach immunoglobulins as capture agents, and the Hb A_{1c} taught by Knowles et al is one type of antigen that can be captured by antibodies.

10. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kornguth et al (US 5,629,213) in view of Roos et al (US 6,008,893).

Kornguth et al reference has been disclosed above, but fails to teach that said solid surface further comprises a plurality of microfluidics channels.

Roos et al teach an instrument with an integrated microfluidic cartridge with a series of channels, in order to deliver sample to a sensor chip for either single or multichannel analysis. See column 1, line 65 to column 2, line 7). In addition, Roos et al teach that the instrument can perform surface plasmon resonance analysis. See column 4, lines 26-56.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Kornguth et al with an instrument with an integrated microfluidic cartridge with a series of channels, as taught by Roos et al, in order to deliver sample to a sensor chip for either single or multichannel analysis. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including an integrated microfluidic cartridge with a series of channels, as taught by Roos et al, in the apparatus of Kornguth et al, since Kornguth et al teach a biosensor with surfaces capable of SPR detection, and the microfluidic cartridge of Kornguth et al is able to deliver fluid to a biosensor that utilizes SPR detection methods.

11. Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornguth et al (US 5,629,213) in view of Cantor et al (US 6,007,987).

Kornguth et al reference has been disclosed above, but fails to teach that said plurality of target molecules comprises at least 50 unique molecules and between 10 and 10000 unique target molecules.

Cantor et al teach an array of 1024 single-stranded probes of a five nucleotide sequence on a hybridization chip, in order to determine the complete sequence of a nucleic acid target. See column 78, lines 35-46 and column 19, lines 33-36.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Kornguth et al with an array of 1024 single-stranded probes of a five nucleotide sequence on a hybridization chip, as taught by Cantor et al, in order to determine the complete sequence of a nucleic acid target. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including an array of 1024 single-stranded probes, as taught by Cantor et al, in the apparatus of Kornguth et al, since Kornguth et al teach an array of nucleic acid capture probes, and the 1024 single-stranded probes of Cantor et al are also nucleic acids.

Although the hybridization of Cantor et al does not require cell solution contacts, as taught by Kornguth et al, the apparatus of Kornguth et al is capable of including a plurality of capture agents, including nucleic acids and immunoglobulins, which would bind to different types of targets simultaneously. Therefore, the apparatus can be applied in the situation wherein the immunoglobulins bind to cellular targets and the nucleic acids bind to nucleic acid targets simultaneously.

In addition, with regards to the instant claim, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to apply an array of at least 50 unique target molecules and in the range between 10 and 10000 unique target molecules, in the apparatus of Kornguth et al, since it has been held that where

the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

12. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kornguth et al (US 5,629,213) in view of Treuter et al (The Journal of Biological Chemistry, 1999).

Kornguth et al reference has been disclosed above, but fails to teach an instruction manual.

Treuter et al teach an instruction manual, in order to teach one to perform SPR analysis using a biosensor. See page 6668, right column, 4th full paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Kornguth et al with an instruction manual, as taught by Treuter et al, in order to teach one to perform SPR analysis using a biosensor. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including an instruction manual, as taught by Treuter et al, in the apparatus of Kornguth et al, since Kornguth et al teach a system with an SPR surface on a biosensor, and the instruction manual of Treuter et al contains instructions on how to use a biosensor for SPR analysis.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 18-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/140,956 in view of Kornguth et al (US 5,629,213).

The instant application recite a system comprising an arrayed solid surface, said solid surface comprising a plurality of addressable target molecules, and a whole cell solution, wherein said whole cell solution contacts said arrayed solid surface.

The copending application teaches a composition comprising an arrayed solid surface, said solid surface comprising an array of transcription factor binding targets (i.e. target molecules), wherein said solid surface is a surface plasmon resonance surface. However, the copending application fails to teach a whole cell solution, wherein said whole cell solution contacts said arrayed solid surface.

Kornguth et al teach an SPR system with nucleic acids that can detect epitopes on bacteria, in order to provide a nucleic acid sensor that can identify bacteria. See column 3, lines 26-38.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of the copending application with nucleic acids that can detect epitopes on bacteria, as taught by Kornguth et al, in order to provide a nucleic acid sensor that can identify bacteria. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including nucleic acid capture agents that can bind to epitopes on bacteria, as taught by Kornguth et al, in the apparatus of the copending application, since the copending application teach nucleic acid binding agents, and the binding agents of Kornguth et al that bind to bacteria are also nucleic acids. Since both the copending application and Kornguth et al teach an array of nucleic acid binding sites on an SPR system, the substitution of nucleic acids that bind to transcription factors for nucleic acids that bind to bacteria is wholly within the capabilities of one of ordinary skill in the art at the time of the invention.

This is a provisional obviousness-type double patenting rejection.

14. Claims 18-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of copending Application No. 10/430,586 in view of Kornguth et al (US 5,629,213).

The instant application recite a system comprising an arrayed solid surface, said solid surface comprising a plurality of addressable target molecules, and a whole cell solution, wherein said whole cell solution contacts said arrayed solid surface.

The copending application teaches a composition comprising an arrayed solid surface, said solid surface comprising an array of transcription factor binding targets (i.e. target molecules).

Kornguth et al teach an SPR system with nucleic acids that can detect epitopes on bacteria, in order to provide a nucleic acid sensor that can identify bacteria. See column 3, lines 26-38.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of the copending application with nucleic acids that can detect epitopes on bacteria, as taught by Kornguth et al, in order to provide a nucleic acid sensor that can identify bacteria. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including nucleic acid capture agents that can bind to epitopes on bacteria, as taught by Kornguth et al, in the apparatus of the copending application, since the copending application teach nucleic acid binding agents, and the binding agents of Kornguth et al that bind to bacteria are also nucleic acids. Since both the copending application and Kornguth et al teach an array of nucleic acid binding sites on an SPR system, the substitution of nucleic acids that bind to transcription factors for nucleic acids that bind to bacteria is wholly within the capabilities of one of ordinary skill in the art at the time of the invention.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

15. Due to the cancellation of claims 1-17, the rejections applied in the previous Office Action, based on 35 U.S.C. 112, second paragraph, are withdrawn.

16. On pages 5-6 of the Remarks, with respect to claim 18, Applicants contend that Kornguth et al do not teach the use of SPR systems for the analysis of solutions containing whole cells and that Kornguth et al do not disclose all the elements of the claimed invention. Specifically, Applicants point to page 5, second paragraph of the previous Office Action for the section that the argument is directed against.

Applicant's arguments have been fully considered but they are not persuasive. Applicant has not convincingly presented the argument as to why Kornguth et al do not teach the analysis of whole cell solutions. Simply stating the traversal of a rejection or stating that the prior art does not teach the limitations of a claim is not sufficient to explain why the prior art fails to teach the claimed limitation. As applied in the previous Office Action and restated in the rejection under 35 U.S.C. 103(a) supra, Kornguth et al teach that the system can detect epitopes on viruses and bacteria. Since the epitopes are explicitly stated to be "on" the bacteria, Kornguth et al includes the situation wherein whole cell bacteria are analyzed by the system, and fully anticipates the claimed limitation of "a whole cell solution".

17. On pages 6-8, Applicants contend that there is no basis for combining Kornguth et al and Magnani et al references. Specifically, Applicants argue that the Examiner's analysis is conclusory because "the Examiner has merely stated what the reference technically teaches...then states 'it would have been obvious to one of ordinary skill in the art' to modify Kornguth with this teaching", and that "this is precisely the type of rejection that the Federal Circuit has forbidden in *In re Lee*".

Applicant's arguments have been fully considered but they are not persuasive. The Federal court's decision in *In re Lee* was made in regards to "common knowledge and common sense" rejections applied by the Board, which were not based on published documentation. Specifically, Applicants point to the section of the decision which states that "The Board's findings must extend to all material facts and must be documented on record". However, by applying Kornguth et al and Magnani et al references, both of which are published documentation, the previous Office Action clearly does not rely on common knowledge or common sense arguments, and Applicant's use of *In re Lee* in traversing the combination of Kornguth et al and Magnani et al is improper. In fact, no rejection against any of the claims has been made that simply relies upon common sense or common knowledge.

Applicant is reminded of the three basic criteria to establish a prima facie case of obviousness, as set forth in the MPEP 706.02(j):

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable

expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

As stated in the previous Office Action and reapplied supra, Magnani et al is applied to teach the specific limitation of "whole stem cell solutions comprising stem cells" (claim 18), wherein text reciting a sample of bone marrow that includes stem cells is relied upon, and meets the criteria (i.e. third criteria) of teaching all the claim limitations. See column 1, lines 17-56 and column 2, lines 25-29. In addition, Magnani et al recite that the bone marrow provides a biological source for bone marrow stem cells and that the stem cells can be isolated to repopulate bone marrow of a cancer patient who has undergone ablative treatment, which provides motivation (i.e. first criteria) for including a sample of bone marrow in the system of Kornguth et al. Restoration of a patient's bone marrow cells through a biological source of stem cells is clear motivation for applying Magnani et al. In addition, since Magnani et al teach that the stem cells can be isolated by CD34 antigens, the reference provides a reasonable expectation of success (i.e. second criteria) for one of ordinary skill in the art to combine Magnani et al with Kornguth et al, since Kornguth et al teach that the system contains immunoglobulins to bind antigens, and CD34 is one type of antigen that can be bound by immunoglobulins.

Therefore, since the previous Office Action and the rejection supra is based on published documents and not common knowledge or common sense, and has

established (1) teaching of each and every claimed limitation, (2) proper motivation to combine references, and (3) a reasonable expectation of success, Applicant's arguments are not considered persuasive and the rejection is maintained.

18. It is also noted that Applicants have not replied to the double patenting rejections made in the previous Office Action.

Conclusion

19. No claims are allowed.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum
Patent Examiner
Art Unit 1641

LYL

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
8/11/05